

Department of Legislative Services
 Maryland General Assembly
 2021 Session

FISCAL AND POLICY NOTE
 Third Reader - Revised

House Bill 1040

(Delegate Kelly)

Health and Government Operations

Education, Health, and Environmental Affairs

Health Occupations - Pharmacists - Administration of Children's Vaccines -
 Study and Temporary Authority

This bill authorizes a licensed pharmacist, from July 1, 2021, to June 30, 2023, to administer a vaccine approved by the U.S. Food and Drug Administration (FDA) to an individual age 3 to 17, if (1) the vaccination is ordered and administered in accordance with the U.S. Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) immunization schedules and (2) the pharmacist meets additional requirements, as specified. The Prevention and Health Promotion Administration (PHPA) in the Maryland Department of Health (MDH), in consultation with the State Board of Pharmacy, must report to specified committees of the General Assembly by December 1, 2021, and December 1, 2022, as specified. **The bill takes effect July 1, 2021. The bill’s vaccination provisions terminate April 30, 2022, if a specified contingency is met.**

Fiscal Summary

State Effect: MDH general fund expenditures increase by *at least* \$100,000 over FY 2022 and 2023 for contractual services for the required reports. Revenues are not affected.

(in dollars)	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	65,000	35,000	0	0	0
Net Effect	(\$65,000)	(\$35,000)	\$0	\$0	\$0

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: The bill does not directly affect local governmental finances or operations.

Small Business Effect: Meaningful.

Analysis

Bill Summary: To administer a vaccine to an individual age 3 to 17, a pharmacist must (1) complete a specified practical training program; (2) have a current certificate in basic cardiopulmonary resuscitation (CPR); (3) complete a minimum of two hours of specified continuing pharmaceutical education related to immunizations; (4) comply with specified recordkeeping and reporting requirements; and (5) inform each child vaccination patient and adult caregiver of the importance of well-child visits with a pediatric primary care provider and refer the patient to such a provider when appropriate.

Reporting Requirements

By December 1, 2021, PHPA must report on the information it determines is important for setting policies for authorizing pharmacists to administer vaccines to children.

By December 1, 2022, PHPA must report on the capacity of the health care system to administer vaccines to children, vaccination rates for children, and community access to the administration of vaccines for children. In completing the report, PHPA must evaluate specified data, study the effectiveness and efficiency of ImmuNet, and consider public health models in which pharmacists can support and facilitate families in obtaining well-child visits from pediatric primary care providers. The report must address specified implementation recommendations and make recommendations regarding whether the temporary authority established under the bill should be made permanent and ways to further integrate the use of ImmuNet in electronic health records to facilitate communication between pharmacists and pediatric primary care providers. In completing the report, PHPA must consult with specified stakeholders and may use available funding to contract with a public health research institution to complete the report.

Termination Contingency

If the *Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19* issued by the U.S. Secretary of Health and Human Services is repealed or expires before January 1, 2022, the bill's vaccination provisions terminate on April 30, 2022. PHPA must notify the Department of Legislative Services within five days after receiving notice of the repeal or expiration of the amendment.

Current Law: An individual must be licensed by the State Board of Pharmacy to practice pharmacy in the State. The practice of pharmacy includes administering vaccinations under specified circumstances.

Per Chapters 559 and 560 of 2011, licensed pharmacists may administer an influenza vaccination to an individual who is at least nine years old, provided the vaccination is administered in accordance with regulations adopted by the State Board of Pharmacy in consultation with MDH. Chapters 255 and 256 of 2013 expanded the authority of pharmacists to administer vaccinations. For individuals 11 to 17 years old, a pharmacist may administer a vaccination listed in the CDC recommended immunization schedule if the individual has a prescription from an authorized prescriber. For adults, a pharmacist may administer a vaccination listed in CDC's recommended immunization schedule or *Health Information for International Travel* if the vaccination is administered under a written protocol that (1) is vaccine specific and (2) meets criteria established in regulation by MDH, in consultation with the boards of pharmacy, physicians, and nursing. A prescription is not required to administer these vaccinations to an individual age 18 or older.

Generally, a pharmacist must document at least one effort to inform the individual's authorized prescriber or primary care provider that a vaccination (other than an influenza vaccination) has been administered.

A May 2020 CDC report found that routine childhood vaccines fell sharply early in the COVID-19 pandemic as doctor's offices closed or reduced hours and parents concerned about exposure to COVID-19 postponed or canceled well-child visits. In response, the U.S. Department of Health and Human Services issued an [order](#) (the *Third Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19*) on August 19, 2020, authorizing any licensed pharmacist with specified training to order and administer any FDA-approved vaccine to children ages 3 to 18. Vaccines must be ordered and administered according to ACIP immunization schedules. The licensed pharmacist must (1) have completed the immunization training that the licensing state requires for pharmacists to order and administer vaccines; (2) have a current certificate in basic CPR; (3) complete a minimum of two hours of continuing pharmacy education during each state licensure period; and (4) comply with state recordkeeping and reporting requirements. The licensed pharmacist must inform childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

State Expenditures: The bill requires PHPA to submit two reports to specified committees of the General Assembly: the first by December 1, 2021 (five months after the bill's effective date) and the second by December 1, 2022. The reports require, among other things, compilation and evaluation of data, a review of ImmuNet, and research on the capacity of the health care system to administer vaccines. PHPA may use available funding to contract with a public health research institution to complete the report.

PHPA advises that it does not currently have the expertise, capacity, staff, data, or resources to research and produce the required reports; furthermore, PHPA resources are already utilized at maximum capacity responding to the COVID-19 pandemic. Thus, PHPA must contract with an organization to complete the required reports.

MDH general fund expenditures increase by *at least* \$100,000 in fiscal 2022 and 2023 for contractual services to complete the report; this analysis assumes expenditures of at least \$65,000 in fiscal 2022 (when the first report is due and much of the work for the second report will be undertaken) and at least \$35,000 in fiscal 2023 (when the work for the second report is concluded). To the extent a contract to complete the reports as specified under the bill requires greater resources, general fund expenditures increase further, potentially significantly.

Small Business Effect: Under the bill, small business pharmacies benefit from the ability to continue administering vaccinations to children as young as age 3 (authority currently granted by the federal government during the COVID-19 pandemic) through June 30, 2023, (or April 30, 2022, if the bill's termination contingency is met). Conversely, other health care providers that currently administer vaccinations may administer fewer vaccinations under the bill.

Additional Information: CDC's [*Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2021*](#) includes vaccinations for hepatitis B; rotavirus; diphtheria, tetanus, acellular pertussis; *haemophilus influenza* type B; pneumococcal conjugate; inactivated poliovirus; influenza; measles, mumps, and rubella; varicella; hepatitis A; tetanus, diphtheria, and acellular pertussis; human papillomavirus; meningococcal; meningococcal B; and pneumococcal polysaccharide.

To date, FDA has approved three COVID-19 vaccines for emergency use. COVID-19 vaccines are currently approved for individuals age 16 and older; however, ACIP will consider recommendations for use when a vaccine is authorized for use in individuals younger than age 16. Maryland began distribution of the vaccines in January 2021.

Additional Information

Prior Introductions: None.

Designated Cross File: SB 736 (Senator Augustine) - Education, Health, and Environmental Affairs.

Information Source(s): U.S. Centers for Disease Control and Prevention; Maryland Department of Health; Department of Legislative Services

Fiscal Note History:
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